REMARKS

The specification has been amended in the first sentence following the title to recite the priority claim to earlier filed applications. Claim 5 has been canceled, and claims 6 and 11 have been amended to recite the phrase "completely complementary". Support for this amendment is found in the specification, for example, at page 10, lines 11-13 which defines complete complementarity between polynucleotide sequences. No new matter is added by these amendments and entry of the amendments is requested.

Restriction Requirement

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (claims 1-2 and 15) drawn to a polypeptide selected from SEQ ID NOs:1-6, and fragments thereof.

Group II (claims 3-4, 9-10, and 13-14) drawn to a polynucleotide encoding the polypeptide.

Group III (claims 5-6 and 11) drawn to polynucleotides that are complementary or that hybridize to a polynucleotide encoding one of SEQ ID NOs:1-6.

Group IV (claims 7-8) drawn to hybridization assays.

Group V (Claim 16) drawn to an antibody that specifically binds the polypeptide.

Group VI (claim 17) drawn to an agonist of the polypeptide.

Group VII (claim 18 drawn to an antagonist of the polypeptide.

Group VIII (claim 19) drawn to a method of treating or preventing a disorder associated with decreased expression of HCHP.

Group IX (claim 20) drawn to a method of treating or preventing a disorder associated with increased expression of HCHP.

The Examiner further stated that the individual proteins of Group I are distinct and are not so linked to form a single general inventive concept under PCT Rule 13.1. The polypeptides comprising SEQ ID NOs:1-6 have different lengths, sequences, structures, and functions. The patentability of each of the claimed proteins would be independent of the patentability of the others. Thus, upon election of one of the above Groups, Applicants must elect a single protein sequence (or polynucleotide encoding it or its complement, etc.) to be examined.

The Examiner stated further that the inventions in Groups I-IX do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

The technical feature linking Groups I-IX appears to be that they all relate to the polypeptide claimed in Group I. In the present case, the main invention (the first mentioned in the claims) is the protein of SEQ ID NO:1.

However, the Examiner stated Bauer et al. (May 1999) discloses a protein having the sequence of SEQ ID NO:1 that Bauer et al teaches is "substantially purified". Thus, the special technical feature linking the inventions of Groups I-IX does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Applicants Response

Applicants hereby elect, with traverse, to prosecute Group II, which includes and is drawn to Claims 3-4, 9-10 and 13-14. Applicants further elect the polynucleoetide sequence of SEQ ID NO:12 With respect to the examination of these claims. Applicants traverse the Restriction Requirement for at least the following reasons.

The unity of invention standard ***must*** be applied in national stage applications

Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides:

> ... [W]hen the Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111....
>
> In applying PCT Rule 13.2 to ... national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2....

Id at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

> Examiners are reminded that unity of invention (not restriction) practice is applicable ... in national stage (filed under 35 U.S.C. 371) applications.

Id at page 1800-149, column 1.

The present application, filed under 35 U.S.C. §371 is a national-stage application; the Examiner is therefore **required** to apply the unity of invention standard.

1. Unity of Invention is accepted between claims to polypeptides and claims to the polynucleotides which encode them

Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT provides that unity of invention is accepted between a protein and the polynucleotide that encodes it:

> *Example 17*
> Claim 1: Protein X.
> Claim 2: DNA sequence encoding protein X.
> Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

Applicants submit that claims drawn to the polypeptide sequence of SEQ ID NO:6 (*i.e.*, claims 1, 2, and 15 of Group I) and claims drawn to the elected polynucleotide sequence of SEQ ID NO:12, which encodes SEQ ID NO:6 (*i.e.*, claims 3-4, 9-10 and 13-14 of Group II), meet the unity of invention requirements. Applicants further submit that with the cancellation of claim 5, and the amendment of claims 6 and 11 to recite "completely complementary", the claims of Group III also meet the unity of invention requirements, and should be examined together with the inventions of Groups I and II.

2. Unity of invention exists with respect to dependent claims in the same claim category as the independent claim from which they depend

MPEP section 1850(A) and 1893.03(d), which recite the provisions of paragraph (c) of Part 1 (entitled "Instructions Concerning Unity of Invention") of Annex B (entitled "Unity of Invention") to the Administrative Instructions Under the PCT, provides:

> **(A) Independent and Dependent Claims.**
>
> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).
>
> (i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, **it does not matter if a dependent claim itself contains a further invention**.... (Emphasis added.)

See MPEP section 1850(A) at page 1800-61. See also MPEP Appendix AI at page 53.

Accordingly, claim16, drawn to antibodies, should also be examined together with claim 1, drawn to the polypeptides from which claim 16 depends. Moreover, claims 3-6 and 17-18, all of which depend from claim 1, are all directed to compositions of matter, *i.e.,* to products. Further, as discussed above, there is unity of invention among claims 1 and 9.

3. Unity of invention exists among all of Applicants' claims

MPEP 1850 provides:

> Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that

> define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Id at page 800-61.

MPEP 1893.03(d) similarly provides:

> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

Id at page 1800-149.

In the present case, unity of invention exists among all of Applicants' claims. The sequences of the claimed polypeptides and the sequences of the claimed polynucleotides encoding those polypeptides are corresponding technical features which are common to all of Applicants claims, which serve to technically interrelate all of Applicants' claims, and which define the contribution over the prior art made by each of them. The Examiner cites art (i.e., Bauer et al., May 1999) alleged to anticipate SEQ ID NO:1. However, SEQ ID NO:1 claims priority to U.S. provisional application Serial No. 60/172,221, filed September 22, 1998, and therefore also defines a contribution over the prior art. In addition, the Examiner cites no art over elected polynucleotide sequence SEQ ID NO:12, or its encoded polypeptide, SEQ ID NO:6. Thus, Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application.

4. The sequences of the claimed polypeptides and the claimed polynucleotides encoding those polypeptides, are corresponding technical features that are common to all of Applicants' claims and that serve to technically interrelate them

The sequences of the claimed polypeptides and corresponding polynucleotides are common to all of Applicants' claims, given that each claim refers to one or both either explicitly or implicitly, by virtue of depending from a claim which makes an explicit reference to the sequences of the claimed polypeptides or claimed polynucleotides.

Moreover, the sequences of the claimed polypeptides and corresponding polynucleotides serve to technically interrelate all of Applicants' claims. Applicants' composition of matter claims 1-6, 9-13, and 15-18) are drawn to either the polypeptides or polynucleotides themselves (1 and 2, drawn to polypeptides, and 3-6 and 9-11, drawn to polynucleotides), to compositions of matter which comprise the polypeptides or polynucleotides as one element (12 and 13, drawn to recombinant polynucleotides and transformed cells, respectively, and 15, drawn to pharmaceutical compositions), or to compositions of matter wherein the sequences of the claimed polypeptides functionally limit the claimed subject matter (Claim 16, drawn to an antibody which specifically binds a polypeptide of claim 1, and claims 17 and 18 drawn, respectively to an agonist and an antagonist of the polypeptide of claim 1).

In Applicants' method claims 7-8, 14, and 19-20, the claimed polypeptides or polynucleotides serve as either the product of the claimed method (claim14, drawn to a method of polypeptide production) and/or as a reagent for performing the method (claims 7 and 8, drawn to methods of detecting a polynucleotide in a sample), and claims 19 and 20 (drawn to a method of treating or preventing a disorder associated with HCHP expression).

Therefore, the claimed polypeptide and polynucleotide sequences are corresponding technical features which are common to all of Applicants' claims, and which serve to technically interrelate them.

Applicants therefore request reconsideration of the Restriction Requirement and examination of all of claims 1-20 with respect to SEQ ID NOs:6 and 12.

CONCLUSION

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

Respectfully submitted,

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